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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,022	07/14/2006	Yasuhiro Nakano	P29235	9439

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EXAMINER
CHRISTIAN, MARJORIE ELLEN

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
08/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/567,022	NAKANO ET AL.	
	Examiner	Art Unit	
	MARJORIE CHRISTIAN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10-13,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. This is the initial Office action based on the application filed February 3rd, 2006.

2. **Claims 1-6, 10-13, 15-16** are pending and have been fully considered.

Election/Restrictions

3. **Claims 7-9, 14** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/6/9.

In Applicant's election of Group 1, **Claims 1-6, 10-13, 15-16** with traverse, Applicant argues that Group I shares a common technical feature with Groups II and III, and because they have a common feature they should be examined together. This is not found persuasive as the claims do not share the same corresponding *special* technical feature (the special technical feature must be a novel feature). Applicant fails to show how any of the limitations are special technical features based on the prior art.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

5. The abstract of the disclosure is objected to because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **Claims 1-6, 10-13, 15-16** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for standard deviations of the pore diameters and thickness within the range shown in the examples and tables, it does not reasonably provide enablement for the larger ranges claimed (see **Claims 1, 3**). These ranges encompass a '0' standard deviation, which would be very improbable if not impossible to achieve. The claimed ranges of the standard deviation (defined as standard deviation over diameter or thickness) include values that are also larger than the pore diameter and membrane thickness and do not enable a person having ordinary skill in the art to make and use the composite membrane without undue experimentation, for example, how can one have a standard deviation of 0.6 for a diameter of 0.1? Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claims 10-13** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: what the capability of removing leukocytes between 1.0 and 3.5 (or 4.0 or more) refers to. Without a unit of measure to provide context the range provided has no significance, the range could be referring to even a minimal amount of leukocyte removal. For the purposes of examination, "a capability of removing between leukocytes between 1.0 to 3.5 (or 4.0 or more) for 450 cm^3 of hemocyte suspension" is being interpreted as "a capability of removing leukocytes from a hemocyte suspension". Additionally, **Claim 13** fails to further limit **claim 10** as it encompasses an entirely different range than **Claim 10**.

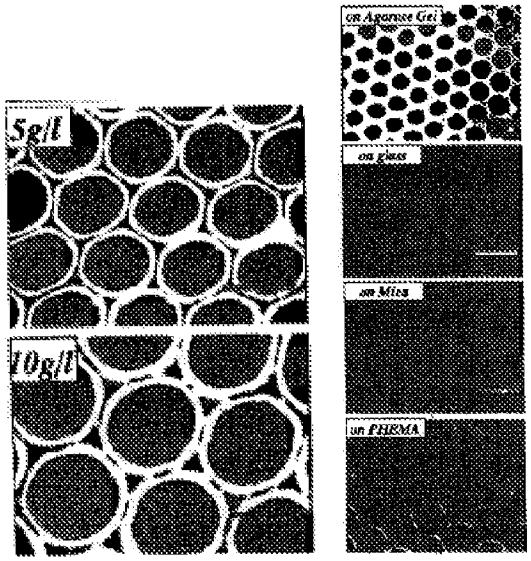
Claim Rejections - 35 USC § 103

8. **Claims 1-6 are rejected under 35 USC 103 (a) as being obvious over JP 2003-149096, TANAKA et al. (hereinafter TANAKA) in view of US PGPub 2003/0150808, MORIKAWA et al. (hereinafter MORIKAWA) as evidenced by US PGPub 2006/0097361, TANAKA et al. (hereinafter '361) and US Patent No. 4,992,485, KOO et al. (hereinafter KOO).**

As to **Claims 1-5**, TANAKA discloses an porous membrane made of organic polymer (Ex. 1-5) for use in blood filtration (Fig. 3, Para. 1) cast on a substrate (Para. 28), wherein the porous membrane (Fig. 3, Para. 1) has an average pore diameter 0.5 to 20 μm (Para. 19), where it is inherent that the pore diameter has a standard deviation that falls within the range of 0 to 0.6 μm, as the standard deviation encompasses a range that includes values higher than the claimed diameter (Para. 32). It appears based on the photomicrograph of TANAKA (shown below Figs. 4-5) and the implicit, well-known structural nature of honeycombed membranes, that the membrane has an opening ratio between 15% and 80%; percentage of through-pores to all the pores of the porous membrane of 30% or more; and a structure in which pores adjacent to one another communicate, as further evidenced by '361 which discloses a side-view of the well-known honeycombed membrane structure (Fig. 2). TANAKA does not appear to expressly disclose having the porous membrane cast onto and penetrating a porous support forming a composite membrane; however it is well known to have honeycomb membranes with well defined pore structures cast (penetrating) a porous support to improve performance and enhance durability for filtration applications, as disclosed by MORIKAWA. MORIKAWA discloses casting an organic resin forming a porous membrane onto a porous substrate (Ex. 1, 2, Fig. 6) to enhance durability of the membrane during filtration (Pg. 1, Para. 4-5). MORIKAWA further discloses that the membrane thickness to pore diameter ratio is in the range of 0.05 to 2 (referring to macrovoid diameter) and average membrane thickness of 0.1 to 20 μm (Ex. 1-2, Comp. Ex. 4), where it is inherent that the standard deviation of membrane thickness would fall

within the standard deviation disclosed, as the range includes values higher than the claimed thickness.

At the time of the invention it would have been obvious to a person having ordinary skill in the art to cast the porous membrane of TANAKA on the porous support of MORIKAWA. The motivation to have a composite membrane comprising a honeycomb membrane penetrating a porous substrate would have been to reduce pressure loss during filtration, improve fluid flow and have a composite membrane with enhanced durability (KOO, C2/L39-59).



As to **Claim 6**, TANAKA (in view of MORIKAWA) discloses the composite porous membrane, where it is inherent that the porous membrane can be used to culture cell solutions, absent evidence to the contrary. As it has been held that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the

prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).*

9. **Claims 10-13 are rejected under 35 USC 103 (a) as being obvious over JP 2003-149096, TANAKA et al. (hereinafter TANAKA) in view of US PGPub 2003/0150808, MORIKAWA et al. (hereinafter MORIKAWA) and US Patent No. 6,645,388, SHEIKH-ALI (hereinafter SHEIKH-ALI).**

As to **Claims 10, 12-13**, TANAKA (in view of MORIKAWA) discloses a leukocyte removal filter device (TANAKA, Para. 1); a plurality of filter elements (TANAKA, Para. 19) and the composite membrane for use in the leukocyte depletion medium as shown in the 103(a) rejection of Claim 1. However, TANAKA (in view of MORIKAWA) does not appear to expressly disclose a prefilter (first filter) at the entrance of the suspension. However, SHEIKH-ALI discloses a prefilter in leukocyte depletion device at the entrance capable of removing leukocytes (C7/L27-30) prior to the other filtration elements at the exit side. At the time of the invention it would have been obvious to a person having ordinary skill in the art to include the prefilter of SHEIKH-ALI in the leukocyte removal device of TANAKA (in view of MORIKAWA). The motivation would have been to remove gel particulates from the hemocyte suspension to improve filtration efficiency.

It would have been obvious to a person having ordinary skill in the art that the composite membranes of TANAKA (in view of MORIKAWA) have a higher effective filtration area (based an increased porosity and uniform pore size) and therefore requires a lesser volume of filter material to obtain the desired degree of leukocyte

removal. It is desirable to have a lower filter volume as it reduces the amount of fluid retained in filter medium. Therefore, it would have been obvious to optimize the volume of the filter element to have a volume between 2 and 18 cm^3 as it has been held obvious to optimize a result effective variable. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to **Claim 11**, SHEIKH-ALI discloses that in order to achieve the desired leukocyte depletion it is necessary to have an effective area of the filter between 4 and 300 cm^2 (C7/L36-37).

10. **Claims 15-16 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 5,665,596, MUSSI et al. (hereinafter MUSSI) in view JP 2003-149096, TANAKA et al. (hereinafter TANAKA) in view of US PGPub 2003/0150808, MORIKAWA et al. (hereinafter MORIKAWA), as evidenced by JP 2001-157574, SHIMOMURA et al. (hereinafter SHIMOMURA).**

As to **Claims 15-16**, MUSSI discloses a cell co-culture device (Fig. 1-4) which divides different cell groups and allows them to come into contact with each other (C4/L50-55); integrated cup-type culture container (12); tube having the cell culture diaphragm adhered to one end (14); and container which can hold the cup-type culture container and culture solution (Fig. 3). MUSSI does not appear to expressly disclose using the membrane of TANAKA (in view of MORIKAWA) as shown in the rejection of **Claim 6** above. However at the time of the invention it would have been obvious to a

person having ordinary skill in the art to use the composite membrane of TANAKA (in view of MORIKAWA) in the apparatus for cell co-culturing as it is well known that the honeycombed membrane structure is better for cultivating cells (SHIMOMURA, Para. 1, 7-10). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/

Primary Examiner, Art Unit 1797

MC